A Single-site Intramural Institutional Certification Memo

To: _____
Name of CCR GPA
National Cancer Institute, Center for Cancer Research, Genomic Program Administrator

From: _____
Name of CCR Scientific Director
National Cancer Institute, Center for Cancer Research Scientific Director

Subject: Certification of the National Cancer Institute Center for Cancer Research Accompany Submission of the Dataset for to an NIH-designated data repository for

The National Cancer Institute, Center for Cancer Research hereby assures that submission of data from _____ for the study entitled
Name of Principle Investigator

_____
Protocol Title
to an NIH-designated data repository meets the following expectations, as defined in Genomic Data Sharing Policy:

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.[1]
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 2.[2]

  The use of aggregate-level data for general research use is not inconsistent with informed consent[3] ☐Yes ☐No

  The display of variant ☐ alleles and/or ☐ frequencies, from this study in public variation archives (i.e., dnSNP and dbVar)[4] is not inconsistent with informed consent. ☐Yes ☐No

- The identities of research participants will not be disclosed to NIH-designated data repositories.

- National Cancer Institute, Center for Cancer Research, Institutional Review Board (IRB) has reviewed the investigator's proposal for data submission and assures that:
  - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.[5]
  - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;[6]
  - Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
  - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
  - The investigator's plan for de-identifying datasets is consistent with the standards outlined in this Policy (see section IV.C.1.).

The data are to be made available through ☐unrestricted[7] or ☐controlled-access[8]

We hereby assure that submission of these data to dbGaP is consistent with the above statements and meets the expectations as defined in the NIH GDS Policy.

	DATE	APPROVAL	NAME (Typed or Printed)	SIGNATURE
Principle Investigator		❒ Yes ❒ No		
Scientific Director/Designee (Signing Official)		❒ Yes ❒ No*		

[1] For the submission of data derived from cell lines or clinical specimens lacking research consent that were created or collected before the effective date of this Policy, the Institutional Certification needs to address only this item.

[2] For guidance on clearly communicating inappropriate data uses, see NIH Points to Consider in Drafting Effective Data Use Limitation Statements, http://gwas.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf

[3] Aggregate-level data include summary statistics from the research study, such as allele frequencies or effect sizes and p-values for test of association. If "yes" is checked, your aggregate-level data will be included in the Compilation of Aggregate Genomic Data, a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request.

[4] The Single Nucleotide Polymorphism Database (dbSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Variant (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: http://www.ncbi.nlm.nih.gov/SNP/ and http://www.ncbi.nlm.nih.gov/dbvar/.

[5] 45 CFR Part 46. Protection of Human Subjects. See http://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/xml/CFR-2011-title45-vol1-part46.xmL

6 As noted earlier, for studies using data or specimens collected before the effective date of this Policy, the IRB, privacy board, or equivalent body should review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.

[7] Data made publicly available to anyone

[8] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.